UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)
March 11, 2013

DP BARCODE(s): 409491

MRID(s) : 49044101

SUBJECT: AW38
(Name of Product)

FILE SYMBOL: 1258-1341

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [ ] OR End-use Product [X]

INGREDIENTS:

PC Code(s)	CAS Number	Active Ingredient(s):
081405	87-90-1	Trichloro-s-triazinetrione
527200	7446-19-7	Zinc sulfate monohydrate

TEST LAB: Analytical & Regulatory Chemistry, Inc.

SUBMITTER: Arch Chemicals, Inc..

GUIDELINE: OCSPP 830.6317 Product Storage Stability
OCSPP 830.6320 Corrosion Characteristics

ORGANIZATION: AD\PSB\CTT

REVIEWER: Earl Goad

APPROVED BY: Karen P. Hicks

DATE APPROVED: March 11, 2013

COMMENT:

3/12/13

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March 11, 2013

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. 1258-1341
Product Name: AW38
DP Barcode(s): 409491

CODE: (570) Conditional Registration Follow-up Data

DATE DUE: May 21, 2013

FROM: Earl Goad, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Monisha Harris PM#32/Killian Swift
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Arch Chemicals, Inc.

PRODUCT FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Trichloro-s-triazinetrione	91.1
Zinc sulfate monohydrate	3.5
Other Ingredient(s):	5.4
Total:	100.0

BACKGROUND:

Arch Chemicals Inc. (a Lonza Company) has submitted a product storage stability and corrosion characteristic studies for their product EPA Reg. No. 1258-1341 "AW38". This product is in the form of a tablet for use as a microbicide (bactericide and algaecide for use in swimming pools.

The data package includes the following:

1. Cover Letter/Transmittal Document dated January 30, 2013.
2. EPA Form 8570-1 Application Form dated January 30, 2013.
3. EPA Form 8570-35: Confidential and Public Product specific data matrix dated January 30, 2013.
4. Product Chemistry Study Document: MRID 49044101 "Miller, R. (2012) Storage Stability and Corrosion Characteristics of AW38. Project Number: ARC/EX/960, ARC/EX/960/010/P/1. Unpublished study prepared by Analytical & Regulatory Chemistry, Inc. 77p"

FINDINGS:

1. In order to evaluate the storage stability the stored product tablets were pulverized and ground to a fine powder for testing. The Trichloro-s-triazinetrione (TCCA) concentrations were determined by titration. Zinc sulfate was quantified using atomic absorption methods performed on an acid digest of the powder.

2. Method validation was performed in each case.

    a. Trichloro-s-triazinetrione (TCCA). Titration.
        i. Precision and linearity were performed using 2-4 replicates each at 5 different concentrations. The mean result was 90.93%(vs label 91.1%) Standard deviation 0.32.
        ii. Accuracy was verified in duplicate with 3 different spike levels. Overall recovery for the three levels was 99.99%

    b. Zinc sulfate. Atomic absorption.
        i. Linearity was measured using seven absorptions determinations (AU) for five different standard levels. The correlation coefficient was 0.9999, slope 0.3055, and Intercept (AU) -0.0008.
        ii. Precision was established by analysis of seven replicates. The average was 3.586% (vs label 3.5%)
        iii. Accuracy by spike recovery at three different levels. The average spike recover was 99.9%

3. Storage stability study was conducted in actual commercial plastic buckets stored at 25 °C. Initially samples were taken then subsequently at 3 month intervals (3, 6, 9, 12 months). The containers were weighed initially and on as they were removed from storage for analysis and inspection inside the container.

   a. Trichloro-s-triazinetrione (TCCA).

   Nominal: 91.1% Certified Limits:88.37-93.83%

Initial	3 Month	6 Month	9 Month	12 Month
90.93%	91.09%	91.11%	91.13%	92.90%

   b. Zinc sulfate.

   Nominal 3.5% Certified Limits 3.325% - 3.675%

Initial	3 Month	6 Month	9 Month	12 Month
3.586%	3.627%	3.601%	3.581%	3.597%

4. Corrosion Characteristics: No changes were observed in the container or its contents. All containers showed a decrease in weight averaging to – 0.06%.

CONCLUSION:

One year storage stability and corrosion characteristics studies were performed in commercial packaging for EPA Reg No. 1258-1341 "AW38". The methods used were validated for accuracy, precision, and linearity and found acceptable. Neither active ingredient showed significant changes in concentration or any evidence of instability. All values remained well within their certified limits. Also no significant changes were observed to the storage container. These studies as provided to support these data requirements are found to be acceptable.